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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,184	12/19/2001	Chad Cori Huval	1932.1064-033	8481

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EXAMINER	
MCMILLIAN, KARA RENITA	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
11/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/025,184	HUVAL ET AL.	
	Examiner	Art Unit	
	KARA R. MCMILLIAN	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3 and 8-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *2,3 and 8-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

No amendments to the claims were submitted in the response filed on October 6, 2008. Claims 2-3 and 8-15 are currently pending.

Response to Arguments

Applicant's arguments filed October 6, 2008 have been fully considered but they are not persuasive.

Applicants argue that Keim is non-analogous art and the reference is therefore improperly relied upon. In response to applicant's argument that Keim is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the Applicants claim a polydiallylamine homopolymer that is cross linked using epichlorohydrin which can be used in a pharmaceutical composition in a solid form such as a tablet or capsule. Keim claims the same resins formed from the reaction of a polydiallylamine cross linked with an epihalohydrin such as epichlorohydrin. Keim does not teach the formulation of these resins into tablets or capsules for pharmaceutical use. McTaggart et al. disclose that at the time of Keim's invention it was not known that said resins could be used as pharmaceutical agents. However, McTaggart et al. teach that since the invention of Keim, it has been discovered that polymeric allylamines are useful as

pharmaceutical agents (see column 1 line 60 through column 2 line 3). Thus one of ordinary skill in the art would be motivated to use Keim's resins as pharmaceutical agents as taught by McTaggart et al.

Applicants also argue that Keim does not teach or suggest that the water soluble resin materials be used to prepare a pharmaceutical composition in a solid form. This argument is found not persuasive because Applicants must consider the rejection as a whole. Keim claims a composition comprising a polydiallylamine cross linked with an epihalohydrin such as epichlorohydrin useful for the wet strengthening of paper. McTaggart et al. teaches that polyallylamine materials while not previously known to be of value in pharmaceutical agents possess useful activity in reducing plasma sterol levels at relatively low dosages and with reduced propensity towards the production of significant side-effects (see column 1 line 60 through column 2 line 3). Thus McTaggart et al. teaches that polyallylamine resins are useful in pharmaceutical compositions. Since Keim et al. discloses polyallylamine resins and McTaggart et al. teaches that polyallylamine resins are useful in pharmaceutical compositions, one of ordinary skill in the art would be motivated to use the polyallylamine resins disclosed by Keim in pharmaceutical compositions as taught by McTaggart et al.

Applicants further argue that claims 14 and 15 of the instant application recite that the polymer is water-insoluble which is more distinct from the teachings of Keim which require that the resin is water-soluble. This argument is found not persuasive since it would be obvious that the resin claimed in Keim would also be water-insoluble since Keim claims the same polydiallylamine homopolymers as claimed in the instant application. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and

its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Furthermore, Keim discloses that the resins are ***fast curing***, water-soluble, and efficient. Once the resins are cured, they not water-soluble. Keim further discloses the resultant products from the curing process in examples 17-23 (column 10) which are not water-soluble.

Applicants further argue that McTaggart et al. does not cure the deficiencies of Keim since the polymers of McTaggart are structurally diverse from the polymers of Keim and the polymers of McTaggart are water-insoluble, while Keim's polymers are water-soluble.

Regarding the argument that the polymers of McTaggart are structurally diverse from the polymers of Keim, as discussed above, McTaggart et al. teaches that polyallylamine materials while not previously known to be of value in pharmaceutical agents possess useful activity in reducing plasma sterol levels at relatively low dosages and with reduced propensity towards the production of significant side-effects (see column 1 line 60 through column 2 line 3). Thus McTaggart et al. teaches that polyallylamine resins are useful in pharmaceutical compositions. Since Keim et al. discloses polyallylamine resins (which are water insoluble once cured) and McTaggart et al. teaches that polyallylamine resins are useful in pharmaceutical compositions, one of ordinary skill in the art would be motivated to use the polyallylamine resins disclosed by Keim in pharmaceutical compositions as taught by McTaggart et al.

Regarding the argument that the polymers of McTaggart are water-insoluble, while Keim's polymers are water-soluble, as discussed above, this argument is found not persuasive since it would be obvious that the resin claimed in Keim would also be water-insoluble since

Keim claims the same polydiallylamine homopolymers as claimed in the instant application and "products of identical chemical compositions cannot have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Furthermore, Keim discloses that the resins are ***fast curing***, water-soluble, and efficient. Once the resins are cured, they not water-soluble. Keim further discloses the resultant products from the curing process in examples 17-23 (column 10) which are not water-soluble.

Finally Applicant's state that reference of *In re Spada* is not understood as this reference would suggest anticipation and not obviousness and that the aqueous solution of water soluble resin described in Keim is not identical to the unit dosage form claimed in the instant application. This reference was provided to explain that identical compositions have identical properties. Since Keim and the instant application claim the same polydiallylamine homopolymers cross linked to an epihalohydrin such as epichlorohydrin, the properties of the resin disclosed in Keim must be the same as those claimed in the instant application. Thus the resins disclosed in Keim would also be water-insoluble.

For the reasons listed above and for reasons of record, the previous rejection of claims 2-3 and 8-15 of the instant application is maintained and reproduced below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-3 and 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keim (US Patent No. 3,700,623) in view of McTaggart et al. (US Patent No. 5,462,730).

Keim et al. teach, in column 1 lines 20-55, water-soluble resinous reaction products of a polymer of a diallylamine and an epihalohydrin such as epichlorohydrin. The resins are fast curing, water-soluble, and efficient. In example 5, 5g of diallyl amine monomer is reacted with 1g of epichlorohydrin cross-linking agent giving a 20% by weight amount of cross-linking agent. In example 6 the polymer to cross-linking agent percentage is 15.9%. In column 2 lines 63-70, Keim et al. teaches that the polymers can be homopolymers or copolymers and can exists as the salts or freebase of the final amines. Keim et al. teach, in col. 3 lines 50-70, that the resinous products are soluble in water and the pH of the solutions can be adjusted to 6 or 5 by addition of hydrochloric, sulfuric, phosphoric, and acetic acids.

Keim does not explicitly teach the resin to be used in pharmaceutical compositions.

McTaggart et al. teaches, in column 1 line 10- column 2 line 40, poly(allylamine)polymeric materials (that can be cross-linked) useful in the formulation of pharmaceutical agents for sequestering bile acid and thus having utility in treating a variety of disorders including hypercholesterolemia, etc…In column 9 line 5 to column 10 line 28, McTaggart et al. teach that the polymeric allylammonium compositions can be formulated in suspensions and as tablets for oral administration. Further the polymeric materials can be prepared as solids and as aqueous and non-solutions based upon the properties of the polymers.

One of ordinary skill in the art at the time the invention was made would recognize that Keim's homopolymer (capable of being neutralized by pharmaceutically acceptable acids) could be formulated into pharmaceutical forms (such as tablets) for oral administration as McTaggart et al. demonstrate that similar polyallylamine polymers can be formulated as such. Further, McTaggart et al. demonstrate that polyallylamine polymers of this type have utility as bile sequestering agents. As the homopolymers Keim details are exactly the polymers currently claimed, the properties the applicant's have discovered are inherently present in Keim's homopolymers. Thus the homopolymers currently claimed were known and similar polymers have already been formulated into pharmaceutical forms for use as bile acid sequestrants.

The addition of new claims 14 and 15 wherein the polydiallylamine homopolymer is water-insoluble does not overcome the fact that the polydiallylamine homopolymers as claimed are still identical to those described in Keim. "Products of identical chemical compositions cannot have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Conclusions

Claims 2-3 and 8-15 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARA R. MCMILLIAN whose telephone number is (571)270-5236. The examiner can normally be reached on Monday-Thursday from 8:30 am- 6:00 pm and every other Friday from 8:30 am- 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kara R. McMillian/
Examiner, Art Unit 1617

KRM

/Shengjun Wang/

Primary Examiner, Art Unit 1617